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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,471

10/13/2006

Hiroyuki Aburatani

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,471	Applicant(s) ABURATANI ET AL.	
	Examiner MEERA NATARAJAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32,34,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32,34,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/2009 has been entered.
2. Accordingly, Claims 29-32, 34 and 36-37 are pending and will be examined on the merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) filed 07/15/2010 has been considered. An initialed copy is enclosed herein.

Claim Rejections Maintained - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. The rejection of Claims 29-32, 34, 36-37 under 35 U.S.C. 103(a) as being unpatentable over Yue et al. (WO/2002/026982, published April 4, 2002, cited on IDS filed 07/17/2006) in view of Ruben et al. (US Patent 7169565) are maintained for the reasons of record.

7. The claims are drawn to a method of diagnosing cancer by detecting C20orf102 protein, which is secreted outside a cell, using an antibody recognizing C20orf102 protein in a blood, serum, or plasma sample from a subject. The C20orf102 protein is described in the specification as amino acid sequence SEQ ID NO:66 and gene sequence SEQ ID NO:2 (see Specification p. 50, 1st paragraph and Table 1, p. 73, No. TEG1).

8. Yue et al. teach a method of diagnosing cell proliferative disorders (e.g. cancers) by detecting nucleic acid and amino acid sequences of secreted proteins. Yue et al. disclose "the invention is based on the discovery of new human secreted proteins (SECP), the polynucleotides encoding SECP, and the use of these compositions for the diagnosis, treatment or prevention of cell proliferative, autoimmune/inflammatory, cardiovascular, neurological, and developmental disorders" (see p. 31, lines 28-31).

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Yue et al. disclose the gene sequence for C20orf102 (SEQ ID NO:2 of the instant application) and the amino acid sequence for C20orf102 protein (SEQ ID NO:66 of the instant application) (see previously attached alignment mailed 11/19/2008). Claim 30 of Yue et al. teach a diagnostic assay comprising combining a biological sample with an antibody which specifically binds to a SECP polypeptide and detecting the complex, wherein the presence of the complex correlates with the presence of the SECP polypeptide in the biological sample (see also p. 59, lines 5-6). Yue et al. disclose “sequences encoding SECP may be used for the diagnosis of disorders associated with expression of SECP” (see p. 60 lines 10-11). Yue et al. disclose several cancers including liver, lung, and pancreas (see p. 60-61). Yue et al. does disclose the term “sample” is used in its “broadest sense” and can comprise a bodily fluid (see p. 29, lines 26-29), however Yue et al. does not specifically disclose a sample comprising blood, serum or plasma. This deficiency is made up for by Ruben et al.

9. Ruben et al. teach a method of identifying polypeptides in a biological sample for the diagnosis of diseases using antibodies directed to said polypeptide. Ruben et al. disclose detecting expression levels of said polypeptides in bodily fluids such as blood serum or plasma (see column 30, lines 48-54).

10. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method taught by Yue et al. of determining the presence of C20orf102 protein using an antibody in samples such as blood, plasma or serum from a subject as taught by Ruben et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success

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based on the teachings of Yue et al. and Ruben et al. because Yue et al. disclose bodily fluids can be used in the method of detecting C20orf102 protein and Ruben et al.

disclose bodily fluids such as blood, plasma and serum can be used in a method to detect polypeptide levels using an antibody directed to said polypeptide. Therefore, Claims 29-37 are obvious over Yue et al. in view of Ruben et al.

Response to Arguments

11. In the response filed 12/28/2009, applicants argue that the interpretation of the term "secreted protein" recited in Yue et al. has a broader meaning including proteins anchored on a cell surface, such as membrane proteins as well as proteins secreted out of the cells. Applicants cite page 83-85 of Yue et al. which discloses assays for "SECP" activity measuring the expression of SECP on the cell surface. Applicants further disclose that Yue et al. suggest "that C20orf102 is a protein anchored on a cell surface but is not a protein secreted out of the cell. In view of the different nature of the two proteins, a person skilled in the art could not combine the C20orf102 protein anchored on a cell surface as disclosed in Yue et al. and a method for detecting a protein present in free form in blood, serum or plasma as disclosed in Ruben et al." (see p. 7, 2nd paragraph of Applicants arguments filed 12/28/2009). In addition, applicants argue Yue et al. discloses expression of the gene coding for the C20orf102 protein and "fails to show expression of the C20orf102 protein and it is well established in the art that the expression level of a gene and the expression level of the corresponding protein are not

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always consistent" (see p.7, last sentence of applicants arguments filed 12/28/2009).

These arguments have been carefully considered but not found persuasive.

12. Yue et al. teach a method of diagnosing cell proliferative disorders (e.g. cancers) by detecting nucleic acid and amino acid sequences of "secreted proteins". Applicants are correct in pointing out that the term "secreted proteins" recited in Yue et al. includes not only proteins secreted out of the cells but proteins anchored on a cell surface as well. However, this clarification of the broad definition of the term "secreted proteins" does not suggest that some of the proteins identified in Yue et al., in particular C20orf102 (based on sequence alignment) is a protein anchored to the cell surface and therefore could not be present in blood, serum or plasma. Yue et al. disclose that SEQ ID NO:3 (which is 100% identical to the amino acid sequence SEQ ID NO:66 identified as C20orf102 in the instant application) contains a signal peptide which mediates protein transportation or secretion (see p.33, lines 12-15). The instant specification discloses on p. 50 (see 1st paragraph) that the secretory signal of C20orf102 protein corresponds to 1 to 24 amino acids in the amino acid sequence represented by SEQ ID NO:66. This would suggest that "SECP-3" identified in Yue et al. as SEQ ID NO: 3 is the same secreted protein (not anchored) as disclosed in the instant application as C20orf102 (SEQ ID NO:66). Furthermore, Yue et al. not only discloses methods of detecting gene expression but protein expression as well. Yue et al. teach "a proteomic profile may also be generated using antibodies specific for SECP to quantify the levels of SECP expression. In one embodiment, the antibodies are used as elements on a microarray, and protein expression levels are quantified" (see p. 65-66). The teachings

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in Yue et al. provide adequate motivation for one of ordinary skill in the art at the time the claimed invention was made to perform the method taught by Yue et al. of determining the presence of secreted C20orf102 protein using an antibody in bodily fluid samples such as blood, plasma or serum from a subject as taught by Ruben et al. Therefore, the rejection of record is maintained.

All previous rejections are withdrawn in view of applicants amendments to the claims in the response filed 12/28/2010.

Conclusion

13. Claims 29-32, 34, 36-37 are rejected.
14. No Claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Friday, 9:00AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Meera Natarajan/
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October 25, 2010